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(54) Dietary supplement

(57) Sources of vitamin B3, B5 and/or B6, D-phenylalanine, glucosamine sulphate and optionally mucopolysaccharides such as chrondroitin sulphate and shark cartilage. The composition can provide relief of joint or muscular pain e.g. arthritis.

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DIETARY SUPPLEMENT

The present invention relates to a dietary supplement having active components which are useful in the relief of joint or muscular pain e.g. in patients suffering from arthritis.

In one aspect the invention provides a composition comprising

(a) vitamin B3, B5 and/or B6;

(b) a source of D-phenylalanine; and

(c) glucosamine sulphate and/or a source thereof,

the components of the composition synergistically reducing the pain in joints or muscles when taken by an affected patient as a dietary supplement.

In an alternative aspect the invention provides a method for making a dietary supplement whose active components can synergistically reduce pain in joints or muscles when the composition is taken by an affected patient over an extended period, said process comprising forming into a unit dosage form (a) vitamin B3, B5 and/or B6, (b) a source of D-phenylalanine and (c) glucosamine sulphate and/or one or more mucopolysaccharides.

The above composition comprises as component (a) pantothenic acid or a salt or ester thereof, conveniently

the calcium salt of pantothenic acid. This material may be partly or completely replaced by nicotinamide or pyridoxine (vitamins B3 and B6). Calcium pantothenate has been reported to relieve the symptoms of rheumatoid arthritis, but at the relatively high daily dose of 2g (see "The Practitioner", February 1980, pages 208 to 211).

D-phenylalanine has been shown to be effective in the treatment of a variety of chronic pain conditions. It is converted slowly in the body to the L-form. It has been postulated that the D-form of phenylalanine, but not the L-form inhibits a number of enzymes which destroy the body's natural pain-killing materials including the enzymes carboxypeptidase A and enkephalinase. The effect of inhibiting these enzymes is that the endorphins naturally produced within the brain have a longer persistence and are therefore able to exert their natural pain-relieving action for more extended periods of time. Again, a daily dose of more than 1 gram of DPLA has been recommended in order to achieve the desired pain reduction effect.

Glucosamine sulphate is an aminomonosaccharide which is naturally present in the body and especially articular cartilages. It has been reported to have a better therapeutic ratio for prolonged treatment of inflammatory

disorders than indomethacin, but again high oral daily doses are required.

The present invention is based on the unexpected discovery that a dietary supplement containing pantothenic acid or a salt or ester thereof, DPA or DLPA and glucosamine sulphate can produce pain relief when taken at relatively low dosages. For example a suitable tablet formulation may contain the following active ingredients

Ingredient	Amount
Pantothenic Acid	100 mg
Shark Cartilage	100 mg
DL-Phenylalanine	50 mg
Chondroitin Sulphate	50 mg
Glucosamine Sulphate	50 mg

The above ingredients may be tabletted with conventional tabletting additives, for example dibasic calcium phosphate, potato starch, ethyl cellulose as glazing agent, stearic acid and magnesium stearate. A recommended daily dose of tablets containing the above mentioned active ingredient is 2-6 tablets daily according to need, typically in many cases about 3 tablets daily.

Further ingredients of the above tablets which are at present believed to act synergistically, but whose presence may be optional, include a mucopolysaccharide such as chrondroitin sulphate. That material is a constituent of cartilaginous tissue and has been demonstrated in vitro to inhibit leucocyte elastase which is an enzyme produced by macrophages and found in high concentrations in the blood and synovial fluid of patients with various rheumatic diseases. It can lead to significant alterations in the constitution of proteoglycans and collogen fibres which are fundamental components of cartilaginous tissue. It has been postulated that the action of chrondroitin sulphate in the present tablets is similar to that of glucosamine sulphate, but that the action of the chrondroitin sulphate is sustained, whereas the glucosamine sulphate produces a more rapid but less sustained physiological response.

It is preferred that there should also be present in the composition a further mucopolysaccharide derived from animal cartilage, especially marine cartilage and in particular shark cartilage. This material when used as a dietary additive is also believed to have beneficial effect on the inflammation which is present in arthritic and rheumatic disorders.

The present composition when employed as a dietary supplement may in some patients give relief of pain in arthritis, rheumatism or chronic back pain.

CLAIMS

1. A composition comprising

(a) vitamin B3, B5 and/or B6;

(b) a source of D-phenylalanine; and

(c) glucosamine sulphate and/or a source thereof,

the components of the composition synergistically reducing pain in joints or muscles when taken by an affected patient as a dietary supplement.

2. The composition of claim 1, wherein the component (a) is a salt or ester of pantothenic acid.

3. The composition of claim 1, wherein the component (a) is calcium pantothenate.

4. The composition of any of claims 1 to 3, wherein the component (b) is DL-phenylalanine.

5. The composition of any preceding claim, wherein there is further present a mucopolysaccharide.

6. The composition of claim 5, wherein the mucopolysaccharide is chrondroitin sulphate.

7. The composition of claim 5 or 6, wherein there is further present a cartilage-derived

mucopolysaccharide.

8. The composition of claim 7, wherein the mucopolysaccharide is shark cartilage.

9. A composition according to any preceding claim, in unit dosage form comprising calcium pantothenate, shark cartilage in a weight approximately equal to that of the calcium pantothenate, and DL-phenylalanine, chrondroitin sulphate and glucosamine sulphate each in about half the amount by weight of the calcium pantothenate.

10. A composition according to any preceding claim in the form of tablets.

11. A process for making a dietary supplement whose active components synergistically reduce the pain in joints or muscles when the composition is taken by an affected patient over an extended period, said process comprising forming into a unit dosage form (a) vitamin B3, B5 and/or B6, (b) a source of D-phenylalanine and (c) glucosamine sulphate and/or one or more mucopolysaccharides.

Patents Act 1977
Examiner's report to the Comptroller under Section 17 (The Search report)

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Relevant Technical Fields

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Databases (see below)
(i) UK Patent Office collections of GB, EP, WO and US patent specifications.

(ii) ONLINE DATABASE WPI CLAIMS, BIOSIS, EMBASE, MEDLINE, JAPIO

Documents considered relevant following a search in respect of Claims :-
1-11

Categories f documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with ne or more other documents of the same category.

A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages	Relevant to claim(s)
	NONE	

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